100. As a result of Defendants' conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendants, and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and restore any money paid for Defendants' misbranded food products by Plaintiff and the Class.

SECOND CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Unfair Business Acts and Practices

101. Plaintiff incorporates by reference each allegation set forth above.

102. Defendants' conduct as set forth herein constitutes unfair business acts and practices.

103. Defendants sold misbranded food products in California during the Class Period.

104. Plaintiff and members of the Class suffered a substantial injury by virtue of buying Defendants' misbranded food products that they would not have purchased absent Defendants' illegal conduct as set forth herein.

105. Defendants' deceptive marketing, advertising, packaging and labeling of their misbranded food products was of no benefit to consumers, and the harm to consumers and competition is substantial.

106. Defendants sold Plaintiff and the Class misbranded food products that were not capable of being legally sold and that were legally worthless.

107. Plaintiff and the Class who purchased Defendants' misbranded food products had no way of reasonably knowing that the products were not properly marketed, advertised, packaged and labeled, and thus could not have reasonably avoided the injury each of them suffered.

108. The consequences of Defendants' conduct as set forth herein outweighs any justification, motive or reason therefor. Defendants' conduct is and continues to be illegal and contrary to public policy, and is substantially injurious to Plaintiff and the Class.

109. As a result of Defendants' conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendants, and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and restore any money paid for Defendants' misbranded food products by Plaintiff and the Class.

THIRD CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Fraudulent Business Acts and Practices

110. Plaintiff incorporates by reference each allegation set forth above.

111. Defendants' conduct as set forth herein constitutes fraudulent business practices under California Business and Professions Code sections § 17200, *et seq.*

112. Defendants sold misbranded food products in California during the Class Period.

113. Defendants' misleading marketing, advertising, packaging and labeling of the misbranded food products was likely to deceive reasonable consumers, and in fact, Plaintiff and members of the Class were deceived. Defendants have engaged in fraudulent business acts and practices.

114. Defendants' fraud and deception caused Plaintiffs and the Class to purchase Defendants' misbranded food products that they would otherwise not have purchased had they known the true nature of those products.

115. Defendants sold Plaintiff and the Class misbranded food products that were not capable of being sold legally and that were legally worthless.

116. As a result of Defendants' conduct as set forth herein, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendants, and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and restore any money paid for Defendants' misbranded food products by Plaintiff and the Class.

FOURTH CAUSE OF ACTION
Business and Professions Code § 17500, *et seq.*
Misleading and Deceptive Advertising

117. Plaintiff incorporates by reference each allegation set forth above.

118. Plaintiff asserts this cause of action for violations of California Business and Professions Code § 17500, *et seq*. for misleading and deceptive advertising against Defendants.

119. Defendants sold misbranded food products in California during the Class Period.

120. Defendants engaged in a scheme of offering misbranded food products for sale to Plaintiff and members of the Class by way of, *inter alia*, product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendants' misbranded food products. Defendants' advertisements and inducements were made within California and come within the definition of advertising as contained in Business and Professions Code §17500, *et seq.* in that such product packaging and labeling, and promotional materials were intended as inducements to purchase Defendants' misbranded food products and are statements disseminated by Defendants to Plaintiff and the Class that were intended to reach members of the Class. Defendants knew that these statements were misleading and deceptive as set forth herein.

121. In furtherance of their plan and scheme, Defendants prepared and distributed within California and nationwide via product packaging and labeling, and other promotional materials, statements that misleadingly and deceptively represented the ingredients contained in and the nature of Defendants' misbranded food products. Plaintiff and the Class necessarily and reasonably relied on Defendants' materials, and were the intended targets of such representations.

122. Defendants' conduct in disseminating misleading and deceptive statements in California and nationwide to Plaintiff and the Class was and is likely to deceive reasonable consumers by obfuscating the true ingredients and nature of Defendants' misbranded food products in violation of the "misleading prong" of California Business and Professions Code § 17500, *et seq*.

123. As a result of Defendants' violations of the "misleading prong" of California Business and Professions Code § 17500, *et seq.*, Defendants have been unjustly enriched at the expense of Plaintiff and the Class. Misbranded products cannot be legally sold and are legally worthless.

124. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendants, and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and restore any money paid for Defendants' misbranded food products by Plaintiff and the Class.

FIFTH CAUSE OF ACTION
Business and Professions Code § 17500, *et seq.*
Untrue Advertising

125. Plaintiff incorporates by reference each allegation set forth above.

126. Plaintiff asserts this cause of action against Defendants for violations of California Business and Professions Code § 17500, *et seq.*, regarding untrue advertising.

127. Defendants sold misbranded food products in California during the Class Period.

128. Defendants engaged in a scheme of offering misbranded food products for sale to Plaintiff and the Class by way of product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendants' misbranded food products. Defendants' advertisements and inducements were made in California and come within the definition of advertising as contained in Business and Professions Code §17500, *et seq.* in that the product packaging and labeling, and promotional materials were intended as inducements to purchase Defendants' misbranded food products, and are statements disseminated by Defendants to Plaintiff and the Class. Defendants knew that these statements were untrue.

129. In furtherance of their plan and scheme, Defendants prepared and distributed in California and nationwide via product packaging and labeling, and other promotional materials, statements that falsely advertise the ingredients contained in Defendants' misbranded food products, and falsely misrepresented the nature of those products. Plaintiff and the Class were the

intended targets of such representations and would reasonably be deceived by Defendants' materials.

130. Defendants' conduct in disseminating untrue advertising throughout California and nationwide deceived Plaintiff and members of the Class by obfuscating the contents, nature and quality of Defendants' misbranded food products in violation of the "untrue prong" of California Business and Professions Code § 17500.

131. As a result of Defendants' violations of the "untrue prong" of California Business and Professions Code § 17500, *et seq.*, Defendants have been unjustly enriched at the expense of Plaintiff and the Class. Misbranded products cannot be legally sold and are legally worthless.

132. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendants, and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and restore any money paid for Defendants' misbranded food products by Plaintiff and the Class.

SIXTH CAUSE OF ACTION
Consumers Legal Remedies Act, Cal. Civ. Code §1750, *et seq.*

133. Plaintiff incorporates by reference each allegation set forth above.

134. This cause of action is brought pursuant to the CLRA. This cause of action does not currently seek monetary relief and is limited solely to injunctive relief. Plaintiff intends to amend this Complaint to seek monetary relief in accordance with the CLRA after providing Defendants with notice pursuant to Cal. Civ. Code § 1782.

135. At the time of any amendment seeking damages under the CLRA, Plaintiff will demonstrate that the violations of the CLRA by Defendants were willful, oppressive and fraudulent, thus supporting an award of punitive damages.

136. Consequently, Plaintiff and the Class will be entitled to actual and punitive damages against Defendants for their violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiff and the Class will be entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of

costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.

137. Defendants' actions, representations and conduct have violated, and continue to violate the CLRA, because they extend to transactions that are intended to result, or which have resulted, in the sale of goods or services to consumers.

138. Defendants sold misbranded food products in California during the Class Period.

139. Plaintiff and members of the Class are "consumers" as that term is defined by the CLRA in Cal. Civ. Code §1761(d).

140. Defendants' misbranded food products were and are "goods" within the meaning of Cal. Civ. Code §1761(a).

141. By engaging in the conduct set forth herein, Defendants violated and continue to violate Sections 1770(a)(5), (7) (9), and (16) of the CLRA, because Defendants' conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that they misrepresent the particular ingredients, characteristics, uses, benefits and quantities of the goods.

142. By engaging in the conduct set forth herein, Defendants violated and continue to violate Section 1770(a)(7) of the CLRA, because Defendants' conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that they misrepresent the particular standard, quality or grade of the goods.

143. By engaging in the conduct set forth herein, Defendants violated and continue to violate Section 1770(a)(9) of the CLRA, because Defendants' conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that they advertise goods with the intent not to sell the goods as advertised.

144. By engaging in the conduct set forth herein, Defendants have violated and continue to violate Section 1770(a)(16) of the CLRA, because Defendants' conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that they represent that a subject of a transaction has been supplied in accordance with a previous representation when they have not.

145. Plaintiff requests that the Court enjoin Defendants from continuing to employ the unlawful methods, acts and practices alleged herein pursuant to Cal. Civ. Code § 1780(a)(2). If Defendants are not restrained from engaging in these practices in the future, Plaintiff and the Class will continue to suffer harm.

SEVENTH CAUSE OF ACTION
Restitution Based on Unjust Enrichment/Quasi-Contract

146. Plaintiff incorporates by reference each allegation set forth above.

147. As a result of Defendants' unlawful, fraudulent and misleading labeling, advertising, marketing and sales of Defendants' misbranded food products, Defendants were enriched at the expense of Plaintiff and the Class.

148. Defendants sold misbranded food products to Plaintiff and the Class that were not capable of being sold or held legally and which were legally worthless. It would be against equity and good conscience to permit Defendants to retain the ill-gotten benefits they received from Plaintiff and the Class, in light of the fact that the products were not what Defendants purported them to be. Thus, it would be unjust and inequitable for Defendants to retain the benefit without restitution to Plaintiff and the Class of all monies paid to Defendants for the products at issue.

149. As a direct and proximate result of Defendants' actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
Beverly-Song Act (Cal. Civ. Code § 1790, *et seq.*)

150. Plaintiff incorporates by reference each allegation set forth above.

151. Plaintiff and members of the Class are "buyers" as defined by Cal. Civ. Code § 1791(b).

152. Defendants are "manufacturers" and "sellers" as defined by Cal. Civ. Code § 1791(j) & (l).

153. Defendants' food products are "consumables" as defined by Cal. Civ. Code § 1791(d).

154. Defendants' nutrient and health content claims constitute "express warranties" as defined by Cal. Civ. Code § 1791.2.

155. Defendants, through their package labels, create express warranties by making the affirmation of fact and promising that their misbranded food products comply with food labeling regulations under federal and California law.

156. Despite Defendants' express warranties regarding their food products, they do not comply with food labeling regulations under federal and California law.

157. Defendants breached their express warranties regarding their misbranded food products in violation of Cal. Civ. Code § 1790, *et seq.*

158. Defendants sold Plaintiff and members of the Class misbranded food products that were not capable of being sold or held legally and which were legally worthless.

159. As a direct and proximate result of Defendants' actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial pursuant to Cal. Civ. Code § 1794.

160. Defendants' breaches of warranty were willful, warranting the recovery of civil penalties pursuant to Cal. Civ. Code § 1794.

NINTH CAUSE OF ACTION
Magnuson-Moss Act (15 U.S.C. § 2301, *et seq.*)

161. Plaintiff incorporates by reference each allegation set forth above.

162. Plaintiff and members of the Class are "consumers" as defined by 15 U.S.C. § 2301(3).

163. Defendants are "suppliers" and "warrantors" as defined by 15 U.S.C. § 2301(4) & (5).

164. Defendants' food products are "consumer products" as defined by 15 U.S.C. § 2301(1).

165. Defendants' nutrient and health content claims constitute "express warranties."

166. Defendants, through their package labels, create express warranties by making the affirmation of fact and promising that their misbranded food products comply with food labeling regulations under federal and California law.

167. Despite Defendants' express warranties regarding their food products, they do not comply with food labeling regulations under federal and California law.

168. Defendants breached their express warranties regarding their misbranded food products in violation of 15 U.S.C. §§ 2301, *et seq.*

169. Defendants sold Plaintiff and members of the Class misbranded food products that were not capable of being sold or held legally and which were legally worthless.

170. As a direct and proximate result of Defendants' actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial.

JURY DEMAND

Plaintiff hereby demands a trial by jury of her claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, and on behalf of the general public, prays for judgment against Defendants as follows:

A. For an order certifying this case as a class action and appointing Plaintiff and her counsel to represent the Class;

B. For an order awarding, as appropriate, damages, restitution or disgorgement to Plaintiff and the Class for all causes of action other than the CLRA, as Plaintiff does not seek monetary relief under the CLRA, but intends to amend her Complaint to seek such relief;

C. For an order requiring Defendants to immediately cease and desist from selling their misbranded food products in violation of law; enjoining Defendants from continuing to market, advertise, distribute, and sell these products in the unlawful manner described herein; and ordering Defendants to engage in corrective action;

D. For all equitable remedies available pursuant to Cal. Civ. Code § 1780;

E. For an order awarding attorneys' fees and costs;

F. For an order awarding punitive damages;

G. For an order awarding pre-and post-judgment interest; and

H. For an order providing such further relief as this Court deems proper.

Dated: April 6, 2012

Respectfully submitted,

By: _____
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Attorneys for Plaintiff

EXHIBIT 1

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Unilever United States, Inc. 8/23/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

August 23,2010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael B. Polk
President of Unilever Americas
Unilever, Inc.
700 Sylvan Avenue
Englewood, NJ 07632-3113

Re: CFSAN-OC-10-24

Dear Mr. Polk:

The Food and Drug Administration (FDA) has reviewed the label for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product and reviewed your labeling for this product on your websites, www.lipton.com[1] and www.liptont.com[2] in August 2010. Based on our review, we have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov[3].

A link to .your website, www.lipton.com[4]. appears on your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product label. This website directs U.S. visitors to another website, www.liptont.com[5]. We have determined that your websites, www.lipton.com[6] and www.liptont.com[7]. are labeling within the meaning of section 201(m) of the Act for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product.

Unapproved New Drug

Your website, www.liptont.com[8]. also promotes your Lipton Green Tea 100% Natural Naturally Decaffeinated product for conditions that cause it to be a drug under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)].

For example, your webpage entitled "Tea and Health," subtitled "Heart Health Research" and further subtitled "Cholesterol Research" bears the following claim: "[F]our recent studies in people at risk for coronary disease have shown a significant cholesterol lowering effect from tea or tea flavonoids ... One of these studies, on post-menopausal women, found that total cholesterol was lowered by 8% after drinking 8 cups of green tea daily for 12 weeks ...."

The therapeutic claims on your website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, your Lipton Green Tea 100% Natural Naturally Decaffeinated product is misbranded under section 502(f)(1) of the Act in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)] .

Unauthorized Nutrient Content Claims

Under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term

"antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

Your webpage entitled "Tea and Health" and subtitled "Tea Antioxidants" includes the statement, "LIPTON Tea is made from tea leaves rich in naturally protective antioxidants." The term "rich in" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

This webpage also states that "tea is a naturally rich source of antioxidants." The term "rich source" characterizes the level of antioxidant nutrients in the product and, therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "rich source" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "tea is a naturally rich source of antioxidants" does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients, as required by 21 CFR 101.54(g)(4). Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

The product label back panel includes the statement "packed with protective FLAVONOID ANTIOXIDANTS." The term "packed with" characterizes the level of flavonoid antioxidants in the product; therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "packed with" could be considered a synonym for a term defined by regulation, nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "packed with FLAVONOID ANTIOXIDANTS" does not comply with 21 CFR 101.54(g)1) because no RDI has been established for flavonoids. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

We note that your label contains a chart entitled "Flavonoid Content of selected beverages and foods." The chart appears to compare the amounts of antioxidants in your product with the amount of antioxidants in orange juice, broccoli, cranberry juice and coffee. However, the information provided may be misinterpreted by the consumer because although the chart is labeled, in part, "Flavonoid Content," the y-axis is labeled "AOX"; therefore, the consumer might believe that the chart is stating the total amount of antioxidants rather than specifically measuring the amount of flavonoids in the product.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Latasha A. Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer A. Thomas
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA New Jersey District

Close Out Letter

- Unilever United States, Inc. - Close Out Letter 5/10/11[9]

Links on this page:

1. http://www.lipton.com/
2. http://www.liptont.com/
3. http://www.fda.gov
4. http://www.lipton.com/
5. http://www.liptont.com/
6. http://www.lipton.com/
7. http://www.liptont.com/
8. http://www.liptont.com/
9. /ICECI/EnforcementActions/WarningLetters/2010/ucm267398.htm

- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- USA.gov
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- State & Local Officials
- Consumers
- Industry
- Health Professionals

 U.S Department of **Health & Human Services**

Links on this page:

1. http://www.lipton.com/
2. http://www.liptont.com/
3. http://www.fda.gov
4. http://www.lipton.com/
5. http://www.liptont.com/
6. http://www.lipton.com/
7. http://www.liptont.com/
8. http://www.liptont.com/
9. /ICECI/EnforcementActions/WarningLetters/2010/ucm267398.htm

EXHIBIT 2

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Dr Pepper Snapple Group 8/30/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

AUG 30 2010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Larry D. Young
President and CEO
Dr Pepper Snapple Group
5301 Legacy Drive
Plano, Texas 75024

Re: CFSAN-OC-10-26

Dear Mr. Young:

The Food and Drug Administration (FDA) has reviewed the label for your Canada Dry Sparkling Green Tea Ginger Ale. We examined the product label and your website at www.canadadry.com [1] in July of 2010. Based on our review, we have concluded that your green tea ginger ale product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov [2].

Your Sparkling Green Tea Ginger Ale is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product label bears a nutrient content claim that is not authorized by regulation. Under section 403(r)(2)(A)(i) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Your Sparkling Green Tea Ginger Ale bears the claim, "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C**" with the double asterisk referring to the statement, "* *Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" on the principal display panel of the product label. In the context of this label the term "enhanced" is an unauthorized synonym for a "more" nutrient content claim. FDA has defined the nutrient content claim "more" and its authorized synonyms in 21 CFR 101.54(e). "More" nutrient content claims may be used on the label or in the labeling of foods to describe the level of nutrients, provided that (1) the food contains at least 10 percent more of the Reference Daily Intake or Daily Reference Value for the nutrient per reference amount customarily consumed than an appropriate reference food, (2) where the claim is based on nutrients that are added to the food, that the fortification is in accordance with the policy on fortification of foods in 21 CFR 104.20, and (3) the claim bears the required information for relative claims as described in 21 CFR 101.130)(2) and 101.54(e)(1)(iii).

Your Sparkling Green Tea Ginger Ale is a carbonated beverage. The policy on fortification in 21 CFR 104.20(a) states that the FDA does not consider it appropriate to fortify snack foods such as carbonated beverages. Additionally, the label of your product does not state the identity of a reference food and the percentage (or fraction) of the amount of the nutrient(s) in the reference food by which the nutrient(s) in the labeled food differs, as is required for "more" nutrient content claims under 101.130)(2). Therefore, even if the term "enhanced" was an authorized synonym for "more," your product would not meet the requirements for a "more" claim under 21 CFR 101.54(e)(1).

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Reference Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activiy (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant Vitamin C," the product must contain 20 percent or more of the RDI for Vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The nutrient content claim for your Sparkling Green Tea Ginger Ale product of "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C** .... **Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" identifies Vitamin C as a nutrient associated with the antioxidant claim. Vitamin C is a nutrient that is a recognized source of antioxidants. Your Nutrition Facts panel declares Vitamin C at 100% of the Daily Reference Value (DRV), which accounts for 60 mg of the claimed 200 mg of antioxidants. According to the nutrient content claim on your product label, the remainder 140 mg of antioxidants must be derived from green tea or green tea flavonoids, which are not nutrients with recognized antioxidant activity under 21 CFR § 101.54(g)(2). Therefore, the claim "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C** .... **Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" does not

meet the requirements of 21 CFR 101.54(g) and misbrands your product under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)).

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Judith G. Dausch, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer Thomas
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA Dallas District

Links on this page:

1. http://www.canadadry.com
2. http://www.fda.gov

- State & Local Officials
- Consumers
- Industry
- Health Professionals

Links on this page:

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EXHIBIT 3

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Redco Foods, Inc. 2/22/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Mr. Douglas N. Farrell, General Manager
Redco Foods, Inc.
One Hansen Island
Little Falls, NY 13365

Re: CFSAN-OC-10-10

Dear Mr. Farrell:

The Food and Drug Administration (FDA) has reviewed the label for your "Salada Naturally Decaffeinated Green Tea" product and your website www.greentea.com. Based on our review, we have concluded that your green tea products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov.

Unapproved New Drug

Your website, www.greentea.com. promotes your green tea products for conditions that cause them to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. Examples of disease claims that cause your products to be drugs include:

On a web page entitled "About Green Tea":

"A Steaming Cup of Medicine" Article:

- "And today, scientific [sic] are ... finding that green tea can ... inhibit the cancer process at virtually every stage, regulate cholesterol levels ... and ward off viruses, fungi and food-borne bacteria."
- "[I]t also helps inhibit dental plaque formation, lower the risk of type 2 diabetes ...."

"The Origins of Tea" Article:

- "By this time, tea was prized as a medicine that could cure digestive disorders ...
- "The tea leaves were also applied externally as a paste to ease the pains of rheumatism."

"Is Green Tea a Brain Food?" Article:

- "[R]ecent studies of the effects of green tea's catechins on animal brains are intriguing:

o "* Less buildup of plaque[.] Finally, mice specially bred to develop Alzheimer's disease developed up to 54% less beta-amyloid buildup in their brains when they were given daily injections of the green tea catechin EGCg.... Beta-amyloid plaques are believed to be a major cause of the brain cell death and dissue [tissue] loss seen in Alzheimer's disease."

The therapeutic claims on your website establish that your green tea products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your green tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201 (p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your green tea products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your green tea products are misbranded under section 502(f)(1) of the Act in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Unauthorized Health Claims

Your green tea products are further misbranded under section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because its labeling bears unauthorized health claims. Your website, www.greentea.com. was reviewed and was found to contain a number of unauthorized health claims, including:

"Green Tea and the FDA: Who's Right?" Article:

- "[O]ver the past 25 years, countless studies showing the positive effect of green tea on several important risk factors for cardiovascular disease have been published in scientific journals."

- "[M]ost studies have shown that green tea reduces certain CVD risk factors with a daily intake of 4-5 cups ...."

The above claims are unauthorized health claims because there is no health claim authorized by regulation or the Act that provides for health claims that characterize the relationship between green tea and cardiovascular disease.

Unauthorized Nutrient Content Claims

Under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The principal display panel of the product label includes the statement "Fortified with Purple Antioxidants [/] Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins ..." In the context of the label, the term "antioxidants" refers, in part, to grapeskins, rooibos (red tea), and anthocyanins. The term "fortified" is defined by regulation and may be used to describe the level of certain substances for which an RDI or Daily Reference Value (DRV) has been established [21 CFR 101.54(e)]. However, there are no RDIs or DRVs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins" is unauthorized and misbrands your product under section 403(r)(1)(A) of the Act.

In addition, nutrient content claims using the term "antioxidant" may only be made for nutrients for which a Reference Daily Intake (RDI) has been established [21 CFR 101.54(g)(1)]. As noted above, there are no RDIs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Purple Antioxidants ... Grapeskins. Rooibos (Red Tea), Anthocyanins" is an unauthorized nutrient content claim that causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The label for this product also bears the unauthorized nutrient content claim "One of the antioxidants known as EGCG (Epigallocatechin gallate) is abundantly found in green tea leaves." This claim is a nutrient content claim because "abundantly found" characterizes the level of EGCG in your product [see section 403(r)(1) of the Act (21 U.S.C. § 343(r)(1)) and 21 CFR 101.13(b)]. Even if we determined that the term "abundantly found" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). This claim does not comply with 21 CFR 101.54(g)(1) because no RDI has been established for EGCG. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Kathleen M. Lewis, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint

Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/S/

Roberta F. Wagner
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA New York District

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 U.S Department of **Health & Human Services**

Links on this page:

EXHIBIT 4

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Fleminger Inc

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Dr. Lee
Dba Dr. Lee's TeaForHealth™
Fleminger Inc.
160 Hawley Lane, Suite 205
Trwnbull, CT 06611

CFSAN-OC-10-01

Dear Dr. Lee:

This is to advise you that the Food and Drug Administration (FDA) reviewed your websites on December 8, 2009 at the Internet addresses www.teaforhealth.com and www.greenteahaus.com. The FDA has determined that your TeaForHealth™ green tea products, Dr. Lee's TeaForHealth® 710EGCG™ inabottle™ Green Tea and Tea For Health® 710EGCG™ Ready-To-Drink Natural Brewed Green Tea, are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(I)], new drugs under section 201(P) of the Act [21 USC § 321(P)], and misbranded under sections 403(a)(1), 403(r)(1)(A), 403(r)(1)(B), and 502(f)(1) of the Federal Food, Drug; and Cosmetic Act (the Act) [21 U.S.C. §§ 343(a)(I), 343(r)(1)(A), 343(r)(1)(B), and 352(f)(1)]. The marketing of the products with these claims violates the Act.

I. Unapproved New Drugs:

Your website, www.teaforhealth.com. redirects the consumer to another site of yours, www.greenteahaus.com. that makes several claims and provides links to articles, brochures, and other "educational materials." Examples of the disease claims observed on www.greenteahaus.com include:

- "Produced according to NCI specifications*" and "Green tea of the NCI-defined strength*" where the asterisks lead the consumer to the text: "Based on the pharmacodynamics data published by the National Cancer Institute (NCI)...daily consumption of 1,200 ml (40 ounces) of green tea containing 710 mcg/ml (-)epigallocatechin gallate (EGCG).. .is equivalent to 1.5 times the lowest anticancer effective dose in a 70-kg (154-lb.) person. Up to 10 times the lowest effective dose can be well tolerated by cancer patients if properly administered."
- "[G]reen tea may be also useful in enhancing the anticancer effects of conventional chemotherapeutics (chemo), even synergistically with the less toxic antineoplastic drugs of the quinolone family, and in controlling Alzheimer's disease, Parkinson's disease, obesity, blood thrombosis, cardiovascular diseases, diabetes ... viral infections, liver damage ... and antibiotic-resistant bacterial infections."
- "As a COX-2 inhibitor, green tea may provide some of the benefits that Vioxx and Celebrex had offered to patients without their toxicities."

Examples of disease claims on www.greenteahaus.com in the form of headings of categorized "educational materials" include:

- "[A]nticancer effects of green tea and the EGCG level of the green tea used in cancer research"
- "Green tea or its components may enhance anticancer effects of drugs and prolong cancer patient survival"
- "Neuroprotection of green tea against Alzheimer's disease and Parkinson's disease"
- "Green tea is anti-thrombotic and may help blood circulation"
- "Antiviral effects of green tea"
- "Liver protection of green tea against hepatitis and other injuries"
- "Green tea enhances the antimicrobial effects of antibiotics, especially that against methicillin-resistant strains of staphylococcus aureus, MRSA"

Your website, www.greenteahaus.com. links to the full text of a brochure entitled, "The Truth in Tea." Examples of disease claims in this brochure include:

- "The anticancer activities of green tea or its components, especially the antioxidants, for example, EGCG, are widely ranged, starting at inhibition of the formation of exogenous carcinogens in the stomach to interference with tumor initiation, promotion and progression."
- "The women drinking 10 Japanese cups (1200-1500 ml) or more green tea a day enjoy an average 8.7 more cancer-free years than low volume tea drinkers do ... The result showed a reduction of breast cancer rate in association with drinking green tea and their dose-dependent relationship...."
- "Heavy green tea consumption was found to be associated with reduced recurrence of breast cancer in [Stage I and Stage II breast cancer] patients ... "
- "[G]reen tea... [was] found to enhance the anticancer effects of certain chemotherapeutic drugs, like 5- fluorouracil and doxorubicin. Thus green tea as dietary supplement may reduce the required dosage of certain anticancer drugs and minimize their adverse side effects."
- "Green tea...has been shown to be potentially beneficial in the fight against viral infections through the following mechanisms:
  - o "Antimutagenic at the molecular level - to reduce the chance of virus mutation. Viral mutation has been a big problem in treating SARS and HIV patients."
  - o "Antiviral at the cellular level (inhibit replication of viral particles, e.g., by interfering with HIV attachment to CD4 lymphocytes).
  - o "Boosting the immunity of the human body (an old concept in Chinese medicine, but quite new in western medicine) against viral and bacterial infections."
  - o "Enhancing the antimicrobial activity of the antibiotics against secondary bacterial infections reducing the chance of developing drug resistance and working synergistically with the antibacterial drugs, such as restoring the MRSA sensitivity to methicillin."

These therapeutic claims on your website establish that the products are drugs under section 201(g)(1) of the Act, because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your products are also "new drugs" under section 201 (P) of the Act, because they are not generally recognized as safe and effective for the above referenced conditions. New drugs may not be legally marketed in the U.S. without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. In addition, your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your products are misbranded under section 502(f)(1) of the Act, in that their labeling fails to bear adequate directions for use.

II. Unauthorized Health Claims:

Examples of health claims observed on www.teaforhealth.com include:

- "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."

Examples of health claims on www.greenteahaus.com in the form of headings of categorized "educational materials" include:

- "Epidemiological and clinical studies on the relationship between cancer risk and the consumption of green tea..."

Examples of health claims in "The Truth in Tea" include:

- "[H]igh consumption of green tea [is] associated with reduced cancer rates of the breast, esophagus, stomach, colon, rectum, pancreas, urinary bladder, prostate, lung, liver, and ovary... "
- "Recent medical research has provided evidence that drinking green tea may reduce the risk of fatal heart attack, stroke, Alzheimer's disease, Parkinson's disease, help reduce body fat and help fight viral infection."

These claims cause your products to be misbranded under section 403(r)(1)(B) of the Act in that they are health claims that have not been authorized by regulation or the Act. In a letter issued to you on June 30, 2005 ("the June 2005 letter"), FDA articulated two health claims for green tea for which FDA intended to consider exercising enforcement discretion:

1. "Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer."
2. "One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggest that drinking green tea may reduce this risks. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer."

The claims presented on your websites are not consistent with either of these qualified health claims.

III. Unauthorized Nutrient Content Claims:

Examples of unauthorized nutrient content claims on www.teaforhealth.com include:

- "Drink high antioxidant green tea -- for your health!"

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of

such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g .. asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidan' activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A) of the Act.

Your claim, "Drink high antioxidant green tea," is an unauthorized nutrient content claim. The term "high" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim is unauthorized and causes your product to be misbranded under section 403(r)(2)(A) of the Act.

IV. False or Misleading Labeling:

Your website, www.teaforhealth.com. makes false or misleading statements regarding FDA's conclusions on the relationship between green tea consumption and cancer risk, including:

- "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."
- "Green tea happens to be one of the components in our diet whose anticancer effects have been supported by solid scientific evidence. The consumers are entitled to the whole truth....The fully disclosed accurate language of the [FDA] granted health claims should read as follows (with my clarifying notes added in parentheses):

  1. 'Two studies **(which were conducted among Japanese living in the northern rural Miyagi prefecture where no tea plantations are in existence)** do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study **(which was conducted among green tea drinking Asian women living in Los Angeles, CA, U.S.A.)** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer **(if a green tea similar to those marketed in northern rural Japan is consumed)**.'

  2. 'One weak and limited study **(which was conducted among Japanese living in the northernmost island of Hokkaido where no tea trees can survive)** does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study **(which was conducted among the local residents of Hangzhou, the traditional green tea plantation and production capital of China)** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer **(if a green tea similar to those marketed in Hokkaido of Japan is consumed)**.",***1***

In the June 2005 letter, FDA informed you of the results of our review of the scientific evidence and other information submitted as part of the petition filed under docket 2004Q-0083 regarding green tea and various cancers. We advised you of our conclusions that there is very limited credible evidence for qualified health claims regarding the consumption of green tea and a reduced risk of prostrate cancer and the consumption of green tea and a reduced risk of breast cancer. We also advised you of our conclusion that there is not credible evidence to support a claim with respect to all other types of cancer. The June 2005 letter articulated FDA's intent to consider exercising enforcement discretion for the two qualified health claims cited in section II above.

FDA worded the conclusions and qualified health claims in the June 2005 letter to reflect our careful evaluation and ranking of the level of scientific evidence linking green tea consumption and the risk of various cancers.***2*** Your statement, "FDA has concluded that there is credible evidence supporting this claim although the evidence is limited," mischaracterizes FDA's conclusions about the level of evidence suggesting green tea reduces the risk of breast and prostate cancers. Moreover, your edits to FDA's conclusions in the qualified health claims' language and your assertions that your edits make the qualified health claims "fully disclosed" and "accurate" suggest that your rendition of FDA's qualified health claims more accurately reflects and more fully discloses FDA's conclusions than FDA's non-embellished version. These statements alter the meaning of FDA's language and misrepresent FDA's conclusions. Thus, these statements cause your products to be misbranded under section 403(a)(1) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your websites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 §§ U.S.C. 332 and 334]. You should take prompt action to

correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include each step that has been or will be taken to completely correct the labeling violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that the correction has been achieved. If applicable, please include a copy of your revised label. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Felicia B. Williams, Compliance Officer, Division of Enforcement, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,
/S/

Roberta Wagner
Director
Office of Compliance
Center for Food Safety and
Applied Nutrition

cc: New England District

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1 http://www.teaforhealth.comIPR/2006/082806.htm

2 For more information on this process generally, see FOOD & DRUG ADMIN., *Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data* (July 2003), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/03N-0069-gdl0001.pdf.

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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EXHIBIT 5

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Oak Tree Farm Dairy, Inc. 16-Aug-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
New York District
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
August 16, 2001
Ref: NYK-2001-113

Richard Classey
Vice President and General Manager
Oak Tree Farm Dairy, Inc.
544 Elwood Road
East Northport, NY 11731

Dear Mr. Classey:

On May 17 and June 5 and 7,2001, we inspected your beverage manufacturing facility located at the above address. During the inspection, we collected a sample of your "OAKTREE REAL BREWED ICED TEA" product and labels for your "OAKTREE FRUIT PUNCH" and "OAKTREE ALL NATURAL LEMONADE" products. Our analysis of the iced tea and review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, Code of Federal Regulations, Part 101 - ,Food Labeling(21 CFR 101).

The "OAKTREE REAL BREWED ICED TEA" is misbranded under Section 403(i)(2) of the Act in that it contains the color additive "FD&C Red No. 40", but the certified color additive fails to be declared on the product label in the statement of ingredients by its specific name, as required (21 CFR 101.22(k)(1)). The product is also misbranded under Section 403(k) of the Act because it contains an artificial coloring that is not declared on the label.

The "OAKTREE FRUIT PUNCH" is misbranded under Section 403(k) of the Act because it contains sodium benzoate and potassium sorbate, which are not declared on the product label. A food to which a chemical preservative is added must declare the common or usual name of that ingredient and a description of its function, e.g., "preservative", as required by 21 CFR 101.226).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your product labels. Other label violations can subject the foods to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration ("FDA").

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

As you know, during the inspection, our investigator also reviewed the labels and formulations for your "OAKTREE ALL NATURAL LEMONADE" and "OAKTREE FRUIT PUNCH". Your lemonade label fails to declare the ingredient, citric acid, which is declared as an ingredient on the label of the lemonade concentrate used to make your lemonade. Further, your fruit punch label fails to declare the ingredients, grape juice, artificial fruit punch flavor, propylene glycol, sodium benzoate, and potassium sorbate, which are declared as ingredients on the label of the fruit punch concentrate used to make your fruit punch. Also, your fruit punch label declares the ingredients, concentrated pineapple juice, gum arabic, glycerol ester of wood resin, and blue 1.

However, these ingredients are not found in the fruit punch concentrate used to make your fruit punch and are not listed as ingredients in your fruit punch formulation. The investigator discussed these labeling discrepancies with you at the conclusion of the inspection.

The term "all natural" on the "OAKTREE ALL NATURAL LEMONADE" label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for "natural," we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993, copy enclosed). FDA?s policy regarding the use of "natural," means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms" 100 % NATURAL" and "ALL NATURAL" on the "OAKTREE REAL BREWED ICED TEA" label because it contains citric acid.

Further, the declaration of potassium sorbate in the ingredient statement on the "OAKTREE ALL NATURAL LEMONADE" label must be followed by a description of its function, e.g., "preservative", as required by 21 CFR 101.22(j).

You should notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions concerning the violations noted, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

/s/
Robert L. Hart
Acting District Director

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 U.S Department of **Health & Human Services**

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EXHIBIT 6

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Hirzel Canning Company 29-Aug-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

August 29, 2001
WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Karl A. Hirzel, President
Hirzel Canning Company
411 Lemoyne Road
Northwood, Ohio 43619

Dear Mr. Hirzel:

During an inspection of you firm on June 13, 2001 our Investigator collected labels for canned tomato products manufactured by your firm. We have limited our review to three of your products, which we have determined to be sufficiently representative of the labeling efficiencies of your products. Our review of the labels collected for the products listed below show that they cause the products to be in violation of Section 403 of the Federal Food Drug , and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

Dei Fratelli CONCENTRATED/ITALIAN STYLE TOMATO PUREE No Salt Added (28 OZ. Cm)

The above product is misbranded within the meaning of Section 403 (a)(l) of the Act in that its labeling 1s false or misleading. The term "FRESH-PACKED" used on the principal display panel, which falsely implies that the finished product in the package is ?fresh," when in fact it has been thermally processed. The Food and drug Administration (FDA) would not object to the use of the term "fresh" in the context of a statement such as "packed from lies tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

Dei Fratelli Fresh & Read CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei ratelli Fresh & Ready CHOPPED MEXICAN TOMATOES & JALAPENOS (14.5 oz. cans)

The above products are misbranded within the meaning of Section 403 a)(1) of the Act in that their labeling is false or misleading. The statements "FRESH- PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products in the package are "fresh," when in fact the have been thermally processed. In addition, according to the ingredient statements, the products contain at east two preservatives. Products that have been thermally processed or that contain preservatives do not meet the definition of "fresh." As stated above, FDA does not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

The Dei Fratelli ® ***. CHOPPED MEXICAN TOMATOES & JALAPENOS product is also misbranded under section 403 (r)((l)(A) of the Act because the label bears the nutrient content claim "HEALTHY," but does not meet the requirements for the claim, as defined in 21 CFR 101.65 (d). Based on the information m the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim may be used where, among other thing, the product contains no more than 360 mg of sodium.

Furthermore, the Dei Fratelli ® *** CONCENTRATED/ITALIAN STYLE TOMATO PUREE, CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS products are misbranded under section 403(r)(l)(A) of the Act because the labels bear nutrient content claims that are not authorize by regulation for the Act or are not consistent with an authorizing regulation. The claims include "** *a great source of Vitamins A and C, and the nutrient Lycopene." In the context used on these labels, the term "great source" is considered to be an unauthorized synonym for "high." FDA has define the nutrient content claim "high" in 21 CFR 101.54(b). ?High" can be used on a food label provided the food contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed.

There is no established reference value for Lycopene; therefore, the claim "*** great source of *** Lycopene" is not authorized. In addition, the Dei Fratelli ® *** CONCENTRATE/ITALIAN STYLE TOMATO PUREE does not contain 20% or more of the RDI of vitamin A and the CHOPPED MEXICAN TOMATOES & JALAPENOS does not contain 20% or more of the RDIs for Vitamin A or C.

Some of the labels for your tomato products have a "NO SALT ADDED" statement on products that are not sodium free. However, the required statement, "not a sodium free food" or "not for control of sodium in the diet" does not appear on the information panel of the labels.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result m enforcement action such as seizure and/or injunction being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should also be aware that the term "fresh" in the ingredient name "FRESH TOMATOES" should not appear in the ingredient statement as part of the common or usual name of an ingredient. Ingredients must be declared b their common or usual & name, as stated in section 403(I)(2) of the Act and 21 CFR 101.4(a)(l). Optional information, such as the term "fresh? is not permitted.

Also, the Dei Fratelli ® *** CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS labels bear the term "All NATURAL," but according to the ingredient statements, calcium chloride and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the ream le to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA?s policy regarding the use "natural", means that nothing artificial or synthetic as been included m, or as been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

Please advise us in writing within fifteen(15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,
Henry Fielden
District Director
Cincinnati District

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U.S Department of **Health & Human Services**

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EXHIBIT 7

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

GMP Manufacturing, Inc. 02-Aug-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510-337-6700

VIA FEDERAL EXPRESS
Our Reference: 2954888
WARNING LETTER
August 2, 2001

Gregory A. Pickett, President
GMP Manufacturing, Inc.
1910 Mark Court, Suite 130
Concord, CA 94520

Dear Mr. Pickett:

We inspected your firm, located at 1910 Mark Court, Suite 130, Concord, California on January 10, 11, and 17, 2001 and found that you have serious violations of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the food and dietary supplement labeling regulations through links in the Food and Drug Administration?s (FDA?s) home page at http://www.fda.gov [1].

The product ProPower is misbranded under Section 403(q)(1) because it does not bear nutrition labeling in accordance with Tide 21, Code of Federal Regulations, Part 101.9 (21 CFR 101.9) Although labeled as a dietary supplement, this product is a conventional food and not a dietary supplement because it is represented as a "nutritionally complete high-protein meal," and a dietary supplement does not include a product that is "represented for use as a conventional food or as a sole item of a meal or the diet. (Section 201(ff)(2)(B) of the Act) The products, Complete Gainer Power, Complete Whey Power, ProPower, Cytomax Exercise and Recovery Drink (Peachy Keen, Cool Citrus, and Apple Berry Flavors), and Cytomax Lite (Lemon Iced Tea Flavor) are misbranded because they contain artificial flavors but are not labeled "artificial" or "artificially flavored." If a food contains any artificial flavor which simulates, resembles or reinforces a characterizing flavor, then the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored." [Section 403(k) of the Act and 21 CFR 101.22(i)(2)]

The products Cytomax Exercise and Recovery Drink (Peachy Keen, Cool Citrus, and Apple Berry flavors) and Cytomax Lite (Lemon Iced Tea Flavor) contain a "supplement Facts" panel. However, the product labels do not identify the products as dietary supplements. If these products are intended to be dietary supplements and not conventional foods, then they must, among other things, be labeled as such in accordance with Sections 201(ff)(2)(C) and 403(q)(5)(F) of the Act and 21 CFR 101.3(g) and 21 CFR 101.36.

The products, Cytomax Exercise and Recovery Drink (Peachy Keen flavor) and Cytomax Lite (Lemon Iced Tea Flavor) are misbranded because they contain colors but are labeled using the term "no artificial colors." Where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a color additive and maybe declared as "Artificial Color," "Artificial Color Added," "Color Added," or an equally informative term that makes clear that a color additive has been used in the food. [Section 403(k) of the Act and 21 CFR 101.22(k)]

The products, Complete Gainer Power, Complete Whey Power, and ProPower are misbranded because the labels bear one or more of the statements, "low lactose," "low in lactose,"" containing L-glutamine, taurine, fat burners and lipotrophics," or "with Herbal Lift!" These statements are unapproved nutrient content claims in that they are made for substances for which no Reference Daily Intakes (RDI?s) or Daily Reference Values (DRV?S) have been established. [Section 403(r)(1)(A) of the Act and 21 CFR 101.13]

The product, Cytomax Exercise and Recovery Drink (Peachy Keen Flavor) is misbranded because the label bears the claim "With anti-oxidants," which is an approved nutrient content claim, but the claim made for the product is not made in accordance with the regulation. [Section 403(r)(I)(A) of the Act and21 CFR 101.54(g)]

The products, Complete Gainer Power and Complete Whey Power, are misbranded because the supplement facts labels do not meet several requirements of the Act or regulations. These violations include the fact that some nutrition information (e.g., the declaration of amounts of amino acids) is declared outside of the supplement facts box, some nutrition information (e. g., calories and carbohydrates) is not presented using the increments required by regulation (e. g., calories and carbohydrates), and nutrition information is given that is prohibited by regulation because the dietary ingredients are present in amounts that maybe declared "zero" (e.g., dietary fiber for the product Complete Whey Power. [Section 403 (q)(5)(F) of the Act and21 CFR 101.36]

Several products are misbranded because they use terms (in the ingredient list) to describe ingredients that are not a part of the common or usual name of the respective ingredients. These terms include "Special ultrafiltered, non-denatured, ultra high quality" and "special ultrafiltered, non-denatured, high quality" for whey protein concentrate and "pre-digested, ion-exchange" for whey protein hydrolysate (Complete Gainer Power and Complete Whey Power), "ion-exchange" for whey protein isolate (Complete ProPower), "Cytosport?s unique complex carbohydrate blend" and "from com hybrids" for amylopectin starches and mahodextrins and "Alpha-L-PolylactateTM" and "our patented non-acidic L-lactate ionically bound to L-arginine, fructose, glycine, L-histidine and Lalanine, sodium L-lactate, potassium L-lactate, L-pyruvate) for L-lactate (Cytomax (Peachy Keen, Apple Berry, and Cool Citrus flavors), and "CytoCarb Lite™ and "Cytosport?s unique low-glycemic indexed combination of pure crystalline fructose and complex carbohydrate blend, including amylopectin starches and branching, short, medium and long linear chain maltodextrins with very low

"DE" (DextroseEquivalence)) for maltodextrins (Cytomax Lite LGI) and Ctyd. [Section 403(i)(2) of the Act and 21 CFR 101.4]

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. We note numerous other labeling violations that we have not included in this letter. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of the labels of your products to assure that they comply with the Actand regulations.

You should know these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your dietary supplement products. If you do not correct these violations, we may not provide certificates to your firm for export of your products to European Union (NJ) countries.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed. Your response should be directed to: Ms. Harurni Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

/s/

District Director

San Francisco District

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